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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,267	08/16/2001	Clinton C.S. Chapple	N1422-005	1973

32905 7590 07/02/2003

JONDLE & ASSOCIATES P.C.
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SUITE 200
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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,267

Applicant(s)

CHAPPLE ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 2-7,9-13,20-22,24 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, SEQ ID NOs: 1, 4, and 6, in Paper No. 10 is acknowledged. Claims 1-26 are pending and Claims 1 and 8 drawn to SEQ ID NO: 4 or 6 are examined. Claims 14-19, 23, and 25 are drawn to non-elected subject material are withdrawn from consideration. Claim 1 is objected to for being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims an isolated DNA encoding a protein having at least 75% sequence identity with the amino acid sequence of SEQ ID NO: 4 or 6 or encoding a polypeptide orthologous to the *Arabidopsis* C3H polypeptide wherein said DNA or a fragment thereof is capable of altering lignin content in a plant.

Applicant describes an isolated DNA from *Arabidopsis* of SEQ ID NO: 1 encoding SEQ ID NO: 4 and 6; and the *ref8* mutant of SEQ ID NO: 1, set forth in SEQ ID NO: 2 encoding SEQ ID NO: 5 and 7.

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Applicant does not describe an isolated nucleic acid sequence or fragments thereof encoding a polypeptide having at least 75% sequence identity to SEQ ID NO: 4, or any other polypeptide orthologous to the *Arabidopsis* C3H of SEQ ID NO: 4.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

Based upon the disclosure of a polynucleotide of SEQ ID NO: 1 encoding SEQ ID NO: 4, there is insufficient relevant identifying characteristics to allow one skilled in the art to completely determine the structure of an isolated nucleic acid sequence or fragments thereof encoding a polypeptide having at least 75% sequence identity to SEQ ID NO: 4, that when expressed in a plant alter the lignin content or composition in a plant, absent further guidance. Since the claimed genus encompasses undisclosed or yet to be discovered DNA sequences that alter lignin content or composition in a plant, the disclosure of SEQ ID NO: 1 encoding SEQ ID

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NO: 4 does not provide adequate description of the claimed genus. In view of the level of knowledge and skill in the art one skilled in the art would not recognize from Applicant's disclosure that Applicant was in possession of an isolated nucleic acid sequence or fragments thereof encoding a polypeptide having at least 75% sequence identity to SEQ ID NO: 4, that alter lignin content or composition when expressed in a plant.

Based upon the disclosure of a polynucleotide of SEQ ID NO: 1 encoding SEQ ID NO: 4, there is insufficient relevant identifying characteristics to allow one skilled in the art to completely determine the structure of a polypeptide orthologous to the *Arabidopsis* C3H of SEQ ID NO: 4, that when expressed in a plant alter the lignin content or composition in a plant, absent further guidance. Since the claimed genus encompasses undisclosed or yet to be discovered DNA sequences that alter lignin content or composition in a plant, the disclosure of SEQ ID NO: 1 encoding SEQ ID NO: 4 does not provide adequate description of the claimed genus. In view of the level of knowledge and skill in the art one skilled in the art would not recognize from Applicant's disclosure that Applicant was in possession of a polypeptide orthologous to the *Arabidopsis* C3H of SEQ ID NO: 4, that when expressed in a plant alter the lignin content or composition in a plant.

Given the failure of an isolated nucleic acid sequence or fragments thereof encoding a polypeptide having at least 75% sequence identity to SEQ ID NO: 4 to be adequately described, or orthologs of SEQ ID NO: 4 to be adequately described methods of its use are also inadequately described. See Written Description Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 "Notices", pages 1099-1111.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 8 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant broadly claims an isolated DNA encoding a protein having at least 75% sequence identity with the amino acid sequence of SEQ ID NO: 4 or 6 or encoding a polypeptide orthologous to the *Arabidopsis* C3H polypeptide wherein said DNA or a fragment thereof is capable of altering lignin content in a plant.

Applicant teaches an isolated DNA from *Arabidopsis* of SEQ ID NO: 1 encoding SEQ ID NO: 4 and 6; and the *ref8* mutant of SEQ ID NO: 1, set forth in SEQ ID NO: 2 encoding SEQ ID NO: 5 and 7.

Applicant does not teach plants transformed with SEQ ID NO: 1, encoding SEQ ID NO: 4 and 6, in either sense or antisense orientation having altered content or composition of lignin.

Altering lignin content or lignin structure by transforming plants with genes known to be involved in lignin biosynthesis produces unpredictable results including plants whose development and morphology have been altered. Hu *et al.* (Nature Biotechnology, 1999, 17:808-812) teach that efforts to reduce tree lignin content by downregulating genes encoding caffeate O-methyltransferase or cinnamyl alcohol dehydrogenase did not succeed (page 808, left

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column, 2nd paragraph). They continue by stating that these results are in agreement with other researchers who tried to reduce lignin content in tobacco.

Moreover, unpredictability in altering lignin in plants is made evident when the pathways and intermediates of the metabolic process in question are not clearly delineated and the models for lignin biosynthesis are still open to a wide range of possible interpretations such that orthologs or enzymes having limited sequence identity to the enzyme in question would not fulfill the expectations predicated by the specification and would require undue experimentation to eliminate non-functional embodiments of the invention given the lack of guidance available to one of skill in the art (Franke R. *et al.*, Plant Journal 2002, Vol. 30, No. 1; pages 33-45; on page 33 2nd column, lines 1-14; page 34 2nd column, lines 12-18; page 40 2nd column, discussion 2nd paragraph; and page 41 1st column, last paragraph to end of discussion). Further, Applicant should note that without an expression step, the method can only be used to decrease lignin and is not enabled for a method “of altering” as commensurate in scope with the claims.

Given the unpredictability in the art as to which substitutions of an isolated polynucleotide encoding a polypeptide having 75% sequence identity to SEQ ID NO: 4 or a fragment thereof; or an isolated DNA encoding a peptide orthologous to the *Arabidopsis* C3H polypeptide or a fragment thereof would be tolerated; the breadth of the claims encompassing an isolated polynucleotide encoding a polypeptide having at least 75% sequence identity to SEQ ID NO: 4, an isolated DNA encoding a peptide orthologous to the *Arabidopsis* C3H polypeptide, or fragments thereof, wherein DNA sequences when expressed in a plant alter lignin content or composition; the lack of guidance in the examples of the specification or in the prior art as to which substitutions or deletions would best serve the invention or which variants of an isolated

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polynucleotide encoding SEQ ID NO: 4 (*Arabidopsis* C3H) would best retain activity in a plant; although one of skill in the art can readily make nucleotide substitutions to a polynucleotide sequence or create fragments one would not know based upon Applicant's disclosure which embodiments would be inoperable and predictably eliminated, and thus undue trial and error experimentation would be needed by one skilled in the art to make and clone a multitude of non-exemplified variants of encoding SEQ ID NO: 4 or an *Arabidopsis* ortholog and would require one of skill in the art to test in a myriad of non-exemplified plants for enhanced expression of a polynucleotide coding sequence to alter the phenotype in a multitude of non-exemplified transformed plant species. Therefore, the invention is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 1, line 3, "complement" is indefinite because it may read upon a single nucleotide. A change to --full length complement-- would obviate this rejection.

At Claim 1, line 1 and line 11, "altering the content or composition of lignin" and altering lignin content". It is not clear whether the amount of lignin is to be increased or decreased or if some unspecified property of lignin is to be enhanced or diminished. Further, it is not clear how content differs from composition. Further, without an expression step the only altering possible is decreasing

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At Claim 1, line 10 "ortholog" is indefinite. It is not clear from the specification what is the definition of ortholog.

Claim 1 recites the limitation "fragment thereof" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiang, V. *et al.* WO 99/31243 published June 24, 1999.

The reference teaches an isolated DNA encoding a protein having at least 75% sequence identity to SEQ ID NO: 4 when expressed in a plant, either in sense or antisense orientation, capable of altering lignin content and composition (see Abstract and pages 9 through 22). Thus the reference teaches all the limitations of the Claims.

All Claims are rejected.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.
June 30, 2003


PHUONG T. BUI
PRIMARY EXAMINER
6/30/03